

Application No. 08/960,557

Docket No.: 50454-56103USCIP

Amendments to the Specification

Please replace the paragraph beginning at page 3, line 25 with the following rewritten paragraph:

In a recent edition of the Journal of the American Medical Association (JAMA), an article appeared which presented research results investigating the liver toxicity problems associated with a sustained release form of nicotinic acid. "A Comparison of the Efficacy and Toxic Effects of Sustained- vs. Immediate-Release Niacin in Hypercholesterolemic Patients", McKenney et al., JAMA, Vol. 271, No. 9, March 2, 1994, page 672. The article presented a study of twenty-three patients. Of that number, [[18]] 12 or [[78]] 52 percent were forced to withdraw because liver function tests (LFTs) increased indicating potential liver damage. The conclusion of the authors of that article was that the sustained release form of niacin "should be restricted from use."

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Please replace Table VIII, beginning at page 42 with the following ~~new table~~ **FAX RECEIVED**

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TABLE VIII
A Comparison of Changes in Liver Function Tests
OFFICE OF PETITIONS

	DOSE							
	0	500	1000	1500	2000	2500	3000	TOTAL
McKenney SR^bNiacin								
AST	23.8	27.9	40.4	36.6	56.5	na	97.0	
%	--	117	170	154	237	na	408	
Invention Dosage^c								
AST	24.3	na	23.7	27.5	26.6	27.6	27.8	
%	--	na	98	113	109	114	114	
McKenney SR Niacin								
AST	25.6	29.5	36.3	39.0	59.1	na	100.0	
%	--	115	142	152	231	na	391	
Invention Dosage								
ALT	21.4	na	18.7	22.6	21.3	22.4	21.8	
%	--	na	87	106	100	105	102	
McKenney SR Niacin								
ALK	95	95	106	105	136	na	135	
%	--	100	112	111	143	na	142	
Invention Dosage								
ALK	74.7	na	73.9	76.1	73.4	76.7	78.0	
%	--	na	99	102	98	103	104	
McKenney SR Niacin								
Drop	--	0	[(2)]1	2	[(7)]4	na	[(7)]5	[(18)]12
n	--	--	--	--	--	--	--	23
%	--	0	[(9)]4	9	[(30)]17	na	[(30)]22	[(78)]52
Invention Dosage								
Drop	--	--	0	0	0	0	0	0
n	--	--	26	67	97	35	15	240
%	--	--	0	0	0	0	0	0
1 year	--	--	15	47	77	31	15	184
1 year	--	--	58	69	79	89	100	77

Dosed twice-per-day as described in "A Comparison of the Efficacy and Toxic Effects of Sustained - vs. Immediate - Release Niacin in Hypercholesterolemic Patients" by McKenney et al., *Journal of the American Medical Association*, March 2, 1994; Vol. 271, No. 9, pages 672-677.

^b SR is "sustained release"

^c Dosed once-per-day at night

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Please replace the paragraph beginning at page 44, line 1 with the following rewritten paragraph:

The results of the comparison of the studies reported in TABLE VIII show that the control group (the McKenney group) had [[18]]12 of 23, or [[78]]52 percent of the patients therein drop out of the test because of an increase in their respective liver function tests. The patients withdrew at the direction of the investigator. In comparison, a group of 240 patients treated according to the present invention had zero patients drop out, based upon the same criteria for withdrawal. The test results reported above indicate that this sustained release dosage form caused no elevation in liver function tests (i.e., no liver damage), no elevations in uric acid and only a small, 7.5% increase in fasting glucose levels which in fact decreased during continued therapy.